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IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF CALIFORNIA

MR. GARY ZIEROTH as the representative of the estate of MRS. SHARON ZIEROTH, *Plaintiff* v. ALEX AZAR, in his capacity as Secretary of the United States Department of Health and Human Services, *Defendant*	Case No. 3:20-cv-00172-MMC PLAINTIFF'S MEMORANDUM IN SUPPORT OF MOTION FOR SUMMARY JUDGMENT Hearing Date: n/a Location: Courtroom 7, 19th Fl., 450 Golden Gate Ave, San Francisco, CA Judge: Honorable Maxine Chesney

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Plaintiff Mr. Gary Zieroth as the representative of the estate of Mrs. Sharon Zieroth files this motion for summary judgment (hereinafter "Mrs. Zieroth"). As detailed in the Complaint and below, Mrs. Zieroth was a Type I diabetic who also suffered from "brittle" diabetes with hypoglycemic unawareness. Mrs. Zieroth's diabetic condition resulted in numerous medical complications. Both to address her underlying diabetes and to protect her against life-threatening hypoglycemia, Mrs. Zieroth's treating physician prescribed a Medtronic MiniMed 530G System, including an insulin pump/receiver and continuous glucose monitor (CGM) and associated insulin pump. As its name implies, a CGM continuously tests glucose levels, alerts the user of out of range values, and, in Mrs. Zieroth's case, communicated with the insulin pump to automatically suspend insulin dosage. In August 2019, Administrative Law Judge Ian Midgley ordered Medicare coverage of Mrs. Zieroth's claims, finding that her CGM was covered "durable medical equipment."

Incredibly, the Secretary (acting through the Medicare Appeals Council) reversed Judge Midgley and denied Mrs. Zieroth's claims on the grounds, among others, that a CGM is not "primarily and customarily used to serve a medical purpose."[1] This non-sensical position has already been rejected by three United States District Courts in decisions that have become final.[2] Indeed, in each of those cases, the court found that the Secretary's position lacked "substantial

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[1] This is so even though the Council decision itself states: "Neither CMS in its referral, nor the Council in this decision, questions the appellant's medical condition, the judgment of her doctors, or the utility of the CGM to her." *See* CAR10.

[2] In *Whitcomb v. Azar*, Case No. 17-cv-14 (E.D. Wisc. Oct. 26, 2017) (Jones, J.), *Bloom v. Azar*, 2018 WL 583111 (D. Vt. January 29, 2018) (Crawford, J.) and *Lewis v. Azar*, 2018 WL 1639687 (D. Mass. April 5, 2018) (Gorton, J.), the district courts found that continuous glucose monitors are entitled to durable medical equipment (DME) Medicare coverage and, in each case, ordered the Secretary to provide CGM coverage.

justification" and ordered the Secretary to pay the plaintiffs' attorneys fees for having to litigate the issue.

Beyond being non-sensical, the Secretary's decision is also based on a Ruling issued, and applied to Mrs. Zieroth, in violation of law. Pursuant to 42 U.S.C. § 1395hh, before the Secretary can issue any rule, requirement, or policy that establishes or changes the rules regarding coverage, the Secretary must comply with the "notice and comment" requirements of the Medicare Act (which are more strict than those under the Administrative Procedure Act). Without complying with those requirements, the Secretary issued CMS 1682-R changing the regulatory requirement by holding that only "therapeutic" CGMs (*i.e.*, those that completely replace the need for finger sticks, in itself incorrect on the facts) would be covered going forward.[3] That Ruling forms the basis for the denial in Mrs. Zieroth's case of Medicare durable medical equipment coverage. That is a violation of the law. Moreover, even taken at face value, the Ruling is not supported by substantial evidence, is arbitrary and capricious, and/or contrary to law.

Mrs. Zieroth's CGM qualifies as covered durable medical equipment and the Council's decision otherwise should be reversed as arbitrary and capricious, contrary to law, and not supported by substantial evidence. This Court should order the Secretary to cover Mrs. Zieroth's claim and remand to the Council with an Order to effectuate the Court's decision.

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[3] All other CGMs (including the Medtronic MiniMed CGM) would be characterized as "non-therapeutic" and not covered. The Ruling also indicated, incorrectly on the law and the facts, that "[i]n all other cases in which a CGM does not replace a blood glucose monitor for making diabetes treatment decisions a CGM is not considered DME." *See* CAR559, CAR567.

I. BACKGROUND

A. Factual Background

Sharon Zieroth was a 72-year old daughter of an Army Lt. Col., wife, mother of two (one adopted), and grandmother to two. Mrs. Zieroth lived in Danville, California with her husband of 48 years (Gary). Previously employed as an executive secretary, Mrs. Zieroth was very active in her church. First diagnosed with Type I diabetes at the age of twenty (20), Mrs. Zieroth was a "brittle" diabetic (*i.e.*, her glucose levels are difficult to control and prone to wild and rapid swings). In addition, Mrs. Zieroth suffered from hypo/hyperglycemic unawareness (*i.e.*, she had no physical sensations – headaches, sweats, etc. –to alert her that her glucose levels need to be adjusted). As a result, Mrs. Zieroth suffered risk of serious injury and death because of her unmanageable diabetic condition. Indeed, prior to receiving a CGM and pump, Mrs. Zieroth had to be revived by paramedics/at the Emergency Room from a diabetic coma at least 12 times as a result of her diabetic condition.

In January 2015, Mrs. Zieroth was prescribed a Medtronic MiniMed 5303G System[4] by her treating physician. A CGM consists of three components: 1) a sensor that is placed under the skin; 2) a transmitter that transmits readings from the sensor; and 3) a receiver that receives signals from the transmitter and displays the computed values and/or takes other actions. Using the sensor, CGMs test glucose levels every 5-7 minutes (*i.e.*, nearly 300 times a day) and report the results to the user. While the actual value is important, the trend of the values (going up or down) and the rate of change are likewise important because it informs the user's treatment decisions regarding what action, if any, must be taken to properly operate the insulin pump.

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[4] The Medtronic MiniMed 530G System is a FDA approved, including without limitation the insulin pump/receiver and Enlite® Sensor continuous glucose monitor. *See* CAR46.

In the case of the Medtronic 530G system, the CGM receiver is integrated into the insulin pump. Thus, the CGM provides extensive data not available from her blood glucose meter that is necessary to properly program Mrs. Zieroth's insulin pump and, for hypoglycemia, to automatically suspend insulin delivery, without user intervention or a user blood glucose meter test, thereby protecting against potentially life-threatening hypoglycemia.

When Mrs. Zieroth was first prescribed a CGM, she was covered by Aetna Insurance. Aetna covered all of Mrs. Zieroth's CGM claims (like, to Plaintiff's knowledge, all other private insurance carriers), including claims denied by Medicare after Mrs. Zieroth's Medicare coverage started on February 1, 2012, until her Aetna coverage expired on December 31, 2015. After January 1, 2016, Mrs. Zieroth's Original Medicare continued denying coverage.

On July 6 and December 14, 2017, and May 16, 2018, Mrs. Zieroth received supplies related to her CGM and insulin pump system, including sensors. Mrs. Zieroth's claims for coverage of the sensors that operate with the CGM system and pump were rejected on the grounds that "Medicare does not pay for this item or service." *See* CAR787, CAR 1672, CAR856.

Thereafter, Mrs. Zieroth sought redeterminations. Mrs. Zieroth's requests for redetermination were denied on May 22 and 30, 2018, and December 5, 2018, respectively, on the grounds that Mrs. Zieroth's CGM did not meet the definition of "therapeutic" in CMS 1682-R and, therefore, that coverage was barred. *See* CAR548-49, CAR1665-66, and CAR2099-2100, respectively. Thereafter, Mrs. Zieroth sought reconsiderations.

Mrs. Zieroth's requests for reconsideration were denied on January 17 and February 19, 2019. *See* CAR493, CAR1274, and CAR2087. Mrs. Zieroth's requests were denied on the grounds that Mrs. Zieroth's CGM was "precautionary" as defined in CMS 1682-R and therefore

non-covered. Thereafter, Mrs. Zieroth filed appeals that were consolidated and assigned to ALJ Ian Midgley.

After conducting a hearing on June 3, 2019, in which CMS chose not to participate, on August 5, 2019, ALJ Midgley issued decisions on ALJ Appeal Nos. 1-8354608581, 1-8354608710, and 1-8354608963 for each of the claims. *See* CAR1679, CAR867, and CAR048, respectively. There, ALJ Midgley held that:

> CMS 1682-R permits therapeutic devices other than the Dexcom G5, and because the Medtronic makes medical decisions and adjusts insulin without human input or additional testing, I do not find it simply a convenience item. The CGM enables Appellant to effectively manage her diabetes and avoid the severe and adverse consequences of her recurrent daily episodes of hypoglycemia. The record demonstrates medical necessity for the CGM disposable sensor and external transmitter and substantial compliance with Medicare's coverage criteria.

Id. at 4.

Thereafter, CMS "appealed" by referring ALJ Midgley's decisions to the Medicare Appeals Council. *See* CAR038. In particular, CMS alleged that ALJ Midgley erred as a matter of law by misapplying CMS 1682-R (the Ruling) with respect to Appellant's CGM sensors. See CAR039.

On December 18, 2019, the Council issued a decision (M-19-3084) reversing ALJ Midgley's decisions and denying coverage. *See* CAR4. As an initial matter, the Council stated: "Neither CMS in its Referral, nor the Council in this decision, questions the appellant's medical condition, the judgment of her doctors, or the utility of the CGM to her." *See* CAR10. Nevertheless, based on CMS 1682-R, the Council concluded with respect to the durable medical equipment coverage claim that Mrs. Zieroth's CGM was not "primarily and customarily used to serve a medical purpose."

As articulated by CMS, though it "does not question … the utility of the CGM" to Mrs. Zieroth, the Secretary is entitled to deference, as "…the agency invested with expertise in the

subject matter…", in his claim that a CGM is not "primarily and customarily used to serve a medical purpose." *See* CAR11-12. In the Secretary's view, the three courts to decide otherwise were wrong and the Article III courts should defer to the Secretary's greater wisdom.

B. Legal Background

1. Standard of Review

Pursuant to 42 U.S.C. § 405(g), the factual conclusions of the Secretary (if supported by substantial evidence) are conclusive.

For all other questions, the Secretary's conclusions should be evaluated using any standard available under the Administrative Procedure Act (*e.g.*, arbitrary and capricious, abuse of discretion, contrary to law, etc.). *See, e.g., Friedman v. Sebelius*, 686 F.3d 813, 826-7 (D.C. Cir. 2012) ("We therefore review the Secretary's decision to exclude the Appellants according to the arbitrary and capricious standard.").

As stated in *Motor Vehicle Mfg Assoc. of the U.S. v. State Farm Automobile Insurance Co.*, 463 U.S. 29 (1983) with regard to the standard for arbitrary and capricious:

> [T]he agency must examine the relevant data and articulate a satisfactory explanation for its action including a rational connection between the fact found and the choice made. In reviewing that explanation, we must consider whether the decision was based on a consideration of the relevant factors and whether there has been a clear error of judgment. Normally, an agency rule would be arbitrary and capricious if the agency has relied on factor which Congress has not intended it consider, entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise.

Id. at 43. (internal citations and quotations omitted).

2. Statutory Construction

With regard to *statutory* construction, the first step is to employ all the traditional rules of construction. *See, e.g., SAS Inst., Inc. v. Iancu*, 138 S.Ct. 1348, 1358 (2018). Only after doing

so, if the Court is unable to discern the meaning and the statute is ambiguous, should the Court consider whether *Chevron* deference should apply to any proposed construction of the statute. *See Chevron, U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837, 842-3 (1984) ("If the intent of Congress is clear, that is the end of the matter; for the court, as well as the agency, must give effect to the unambiguously expressed intent of Congress.").[5] Even if a statute is ambiguous, a court should only accord deference to "reasonable" constructions offered by an agency. *Id.* at 844. "Where the agency interprets a statute in a way that flatly contradicts Congress's express purpose, the court may – indeed, must – intervene and correct the agency." *See Common Cause v. Fed. Elec. Comm'n*, 692 F.Supp. 1391, 1396 (D.D.C. 1987).

3. Regulatory Construction

With regard to *regulatory* construction, again, the first step is to employ all the traditional rules of construction. *See Kisor v. Wilkie*, 139 S.Ct. 2400, 2415-6 (2019).[6] If, after doing so, the regulation is not ambiguous, then that is the end of the inquiry and the Court should give effect to the regulation. As stated in *Kisor*:

> First and foremost, a court should not give *Auer* deference unless the regulation is genuinely ambiguous. If uncertainty does not exist, then there is no plausible reason for deference. The regulation just means what it means – and the court must give it effect, as the court would any law.
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> But if the law gives an answer – if there is only one reasonable construction of a regulation – then a court has no business deferring to any other reading, no matter how much an agency insists it would make more sense. Deference in that circumstance would "permit the agency, under the guise of interpreting a regulation, to create a *de facto* new regulation."

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[5] No doubt, the Court is aware of the very substantial debate (even among members of the Supreme Court) as to the continued viability of *Chevron*.

[6] As stated in *Kisor* itself, there is very substantial debate (even among members of the Supreme Court) as to the continued viability of *Auer*.

Id. (internal citations omitted). Conversely, if the regulation is still ambiguous, deference to "reasonable" constructions offered by an agency may be appropriate in certain circumstances. *Id.* at 2415-6 ("If genuine ambiguity remains, moreover, the agency's reading must still be 'reasonable'."). Constructions which are arbitrary, capricious, or manifestly contrary to a statute or regulation are not reasonable. *See Chevron*, 467 U.S. at 844.

4. Durable Medical Equipment

Medicare covers "durable medical equipment." Pursuant to 42 U.S.C. § 1395x(n), "durable medical equipment" is not defined, except by a non-exhaustive list of examples. One specific example cited is "blood glucose monitors."

The Secretary has, after proper notice and opportunity for public comment, issued regulations further setting forth a five-part test to determine whether equipment is "durable medical equipment." *See* 42 C.F.R. § 404.202. Equipment is considered "durable medical equipment" if it:

a) Can withstand repeated use;
b) Has an expected life of at least 3 years;
c) Is primarily and customarily used to serve a medical purpose;
d) Generally is not useful to an individual in the absence of illness or injury; and
e) Is appropriate for use in the home.

The Secretary clarified this test, also with proper notice and opportunity for comment, with respect to multi-component systems, like the Medtronic MiniMed 530G System. (76 Fed. Reg. 70291).

5. Prior Litigation

The issue of whether a CGM qualifies as durable medical equipment has been litigated multiple times. In sum, the Secretary has refused to cover CGMs on the grounds: 1) that CGMs do not comply with the non-statutory/non-regulatory term "precautionary"; and/or 2) that CGMs do not serve a "primary medical purpose" (as opposed to the regulatory phrase "primarily …

used to serve a medical purpose"). Those bases for denying CGM claims have been litigated in three district court cases.

In *Whitcomb v. Azar*, Case No. 17-cv-14 (E.D. Wisc. Oct. 26, 2017) (Jones, J.), *Bloom v. Azar*, 2018 WL 583111 (D. Vt. January 29, 2018) (Crawford, J.) and *Lewis v. Azar*, 2018 WL 1639687 (D. Mass. April 5, 2018) (Gorton, J.), the district courts found that the Secretary's claim that a CGM is not "primarily and customarily used to serve a medical purpose"/was "precautionary" was erroneous, not supported by substantial evidence and/or was arbitrary and capricious. In each case, the court determined that CGMs are entitled to coverage as durable medical equipment and ordered the Secretary to provide CGM coverage. Each of those decisions is final. Moreover, in each of those cases, the court further found that the Secretary's position lacked "substantial justification" and ordered the Secretary to pay the plaintiffs' attorney fees for having to litigate the issue.

In addition, the Secretary's own Civil Remedies Division concluded that the Secretary's claim that a CGM was not covered as "precautionary" did not meet the "reasonableness standard." *See Lewis v. Azar,* DAB No. CR4596, WL 2851236 at *18 (2016) (reversed on other grounds).

6. Notice and Comment Requirements

Pursuant to 42 U.S.C. § 1395hh(a)(2):

> No rule, requirement, or other statement of policy (other than a national coverage determination) that establishes or changes a substantive legal standard governing the scope of benefits, the payment for services, or the eligibility of individuals, entities, or organizations to furnish or receive services or benefits under this subchapter shall take effect unless it is promulgated by the Secretary by regulation under paragraph (1).

The "paragraph (1)" referred to requires the Secretary to issue such rules, requirements or other statements of policy in the form of regulations.

Pursuant to 42 U.S.C. § 1395hh(b)/(c), proposed regulations must be published in the FEDERAL REGISTER and the public provided no less than 60 days to comment on the proposed regulations before the regulations may be published as final regulations.

In *Azar v. Allina Health Services*, 139 S.Ct. 1804 (2019), the Supreme Court held that the Medicare specific notice and comment provisions (rather than the APA' notice and comment provisions) apply to Medicare. *Id.* at 1809. Two differences between notice and comment under the Medicare Act and under the APA are: 1) the substantive/interpretive distinction under the APA does not apply to the Medicare Act; and 2) the Medicare Act requires 60 days of notice and comment rather than the 30 days under the APA. Thus, under § 1395hh, no rule, requirement, or statement of policy that establishes or changes the standard for paying for services/benefits can take effect until the notice and comment provisions have been complied with.

In applying the statute as explained in *Allina*, courts have stricken LCDs adopted by the Secretary without notice and comment under very similar circumstances. For example, in *Agendia, Inc. v. Azar*, 420 F.Supp.3d 985 (S.D. Cal. 2019) (appeal pending) the Court set aside a Medicare Appeals Council decision that denied coverage based on an LCD issued without notice and comment. *Id.* at 995-98.

7. **CMS 1682-R/LCD L33822**

Without prior notice and comment, on January 12, 2017, the Secretary issued CMS 1682-R. As stated, "CMS Rulings are decisions of the Administrator that serve as precedent final opinions and orders and statements of policy and interpretation." *Id.* at 1. There, the Secretary maintained, incorrectly on the facts, that any CGM which did not completely replace finger sticks was "precautionary" and not covered. The Secretary asserted that if the reading from a

CGM sensor had to be confirmed with a finger stock prior to making a treatment decision, the CGM was not "primarily and customarily used to serve a medical purpose." *Id.* at 6-7.

Conversely, CGMs which do replace finger sticks the Secretary labeled "therapeutic" and considered covered. By its own terms, CMS 1682-R was effective as of the very date it issued – *i.e.*, January 12, 2017. As described in the Council's decision, this is a "coverage policy for CGM's and ancillary equipment." *Id.* at 9.

Effective the same day, and also without notice and comment, CMS 1682-R was incorporated into LCD L33822.

II. DISCUSSION

The Secretary's denial of Mrs. Zieroth's claim should be reversed (and coverage ordered) because CMS 1682-R was issued in violation of law and/or because the assertion that a CGM is not "primarily and customarily used to serve a medical purpose" is not supported by substantial evidence, is arbitrary and capricious, and is contrary to law. Likewise, the idea that a CGM is not a "blood glucose monitor" within the meaning of the statute is flawed.

A. The Denial Based on CMS 1682-R Should Be Reversed[7]

The denial of Mrs. Zieroth's claim should be reversed because CMS 1682-R was issued in violation of law, is not supported by substantial evidence, is contrary to law, and/or is arbitrary and capricious.

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[7] These arguments are equally applicable to LCD L33822, which refers to Policy Article A52464, which expressly incorporates CMS 1682-R. Like CMS 1682-R, LCD L33822 and Policy Article A52464 issued on January 12, 2017, without complying with the notice and comment requirements of 42 U.S.C. § 1395hh. Likewise, LCD L33822 and Policy Article A52464 are not supported by substantial evidence/are arbitrary and capricious. In any event, while the Council's decision refers to LCD L33822 and Policy Article A52464 in the "Legal Background" section, the "Discussion" section comprising the Council's decision refers only to CMS 1682-R. Thus, the present motion focusses on the actual basis for the Council's decision – CMS 1682-R. Should the Court choose to consider LCD L33822 and Policy Article A52464, the same arguments apply.

1. CMS 1682-R Issued In Violation of Law/ Denial Based on CMS 1682-R Is Unlawful

As detailed above, without prior notice and comment (including publication in the FEDERAL REGISTER), CMS 1682-R issued on January 12, 2017, effective as of that very day. That was a violation of 42 U.S.C. § 1395hh.

As stated in 42 U.S.C. § 1395hh(a)(2), "[n]o rule, requirement, or other statement of policy" that establishes or changes a standard concerning the scope of benefits, payment for services, etc. shall take effect unless promulgated by regulation issued in accordance with the notice and comment provisions. On its face, CMS 1682-R describes itself, *inter alia*, as a "statement[] of policy and interpretation." *See* CAR553. Further, of course, by setting forth the standard of "precautionary" (non-therapeutic) and "therapeutic" CGMs, CMS 1682-R purports to establish or change the standard concerning the scope of benefits, payment for services, or eligibility of individuals receiving a CGM. Thus, under § 1395hh, CMS 1682-R cannot "take effect unless it is promulgated by the Secretary by regulation" (including compliance with the notice and comment provisions). *See* 42 U.S.C. § 1395hh.

Here, there is no genuine issue of material fact that the Secretary did not comply with the notice and comment provisions. Nothing was published in the FEDERAL REGISTER concerning proposed regulations, there was no opportunity for the public to comment, and there was no publication of final regulations. *See* 42 U.S.C. § 1395hh(b). Instead, in defiance of the statute, the Secretary simply issued a ruling establishing a new standard for benefits and, relying on that

illegal standard, proceeded to reject claims (including Mrs. Zieroth's) on that basis. *See* CAR13 ("We, like the ALJs, are bound by CMS Rulings.", *citing* 42 C.F.R. § 405.1063(b)).[8]

Thus, CMS 1682-R issued in violation of law and the denial of Mrs. Zieroth's claim based on CMS 1682-R was unlawful, should be reversed, and coverage ordered.

This case is very similar to the *Agendia* case where, again, an LCD issued without notice and comment and was used by the Medicare Appeals Council to reject claims. The court in Agendia held that the LCD was invalid and reversed the denial of the claim.

This court should do the same.

2. CMS 1682-R Is Not Supported By Substantial Evidence/ Is Arbitrary and Capricious/Contrary to Law

Independent of invalidity due to the Secretary's failure to provide notice and opportunity to comment, CMS 1682-R is also an improper basis for denial of Mrs. Zieroth's claims because CMS 1682-R is not supported by substantial evidence, is arbitrary and capricious, and is contrary to law.

a) A Construction of "Durable Medical Equipment" That Excludes CGMs Is Erroneous

As noted above, the statute indicates that "durable medical equipment" is a covered benefit. *See* 42 U.S.C. § 1395x(n). As detailed above, even to the extent that it is determined that "durable medical equipment" is ambiguous, when the agency offers a construction that contradicts Congress' purpose, the Court must correct the agency. *Common Cause*, 692 F.Supp. at 1396.

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[8] In this regard, 42 C.F.R. § 405.1063(b) indicates that CMS Rulings are "published" and further indicates that "consistent with 401.108", they are binding on "all CMS components, [and] on all HHS components that adjudicate matters under the jurisdiction of CMS[.] As set forth in 42 C.F.R. § 401.108(a), like 42 U.S.C. § 1395hh, it is contemplated that any such Rulings will be published in the FEDERAL REGISTER. Here, again, it is undisputed that that did not occur.

Here, in CMS 1682-R, the Secretary offers a construction of the phrase "durable medical equipment" that improperly establishes a category of "non-therapeutic" CGM that is incorrect on the facts and that arbitrarily and capriciously is used to deny Medicare coverage for the life-saving CGM that also protects Mrs. Zieroth, where it is undisputed that the Medtronic MiniMed 530G System is "durable." Thus, whatever the phrase "durable medical equipment" means, the Secretary's construction contradicts Congress' purpose and must be rejected. *See, e.g., Mayo Found. For Med. Educ. & Research v. U.S.*, 562 U.S. 44, 53 (2011) ("manifestly contrary to the statute").

For the same reasons, the Secretary's proposed "therapeutic/non-therapeutic" construction is not supported by substantial evidence. There is simply no evidence that Mrs. Zieroth's Medtronic MiniMed 530G System, including CGM, is not "durable medical equipment" or that her CGM is not medically therapeutic and primarily used to serve a medical purpose. A CGM cannot make waffles, wash a car, or do Westlaw searches. Indeed, CMS 1682-R confirms that the receiver portion of a CGM is, in fact, "durable" as the Secretary defines it. *See* CMS 1682-R at 10.

Likewise, the Secretary's construction of "durable medical equipment" as excluding a CGM other than the Dexcom G5 is arbitrary and capricious. The Secretary's view is both counter to the evidence before the agency as to the function and qualities of not only the Dexcom G5 but also other CGM and is so implausible that it cannot be ascribed to a difference in view or the product of agency expertise. *State Farm*, 463 U.S. at 43.

At the end of the day, the Secretary's proposed construction of "durable medical equipment" excluding CGMs as "non-therapeutic" is not reasonable and must be rejected. *Chevron*, 467 U.S. at 844. This is especially the case where the Secretary's alleged basis for

distinction between covered and non-covered CGMs (*i.e.*, "therapeutic" replacement of finger sticks/"non-therapeutic" "precautionary", respectively) has no basis on the facts or in the statute - which indicates coverage of "durable medical equipment" and is not dependent on whether finger sticks are eliminated or not.

b) A Construction of "Primarily and Customarily Used to Serve a Medical Purpose" That Excludes CGMs Is Erroneous

The Secretary had, prior to issuing CMS 1682-R without notice and comment, issued regulations, after proper notice and comment, clarifying what is considered "durable medical equipment" including a five-part test. *See* 42 C.F.R. § 404.202. In CGM cases, including this one, the Secretary has contended that CGMs are not "primarily and customarily used to serve a medical purpose" but has not disputed that CGMs meet the other four factors.

With regard to "primarily and customarily used to serve a medical purpose", as noted in *Kisor*, the first step is to determine whether the provision is "genuinely ambiguous." *Kisor*, 139 S.Ct. at 2415-6. If the provision is not ambiguous, deferring to any proposed construction by the agency "would permit the agency, under the guise of interpreting a regulation, to create a *de facto* new regulation." *Id.*

Here, neither the Council decision nor CMS 1682-R contend that "primarily and customarily used to serve a medical purpose" is ambiguous and, indeed, it is not. As the court in *Whitcomb* noted, "The regulation defining durable medical equipment, as that term is used in the Act, is clear on its face." *Whitcomb,* at 11. Thus, because the provision is not ambiguous, "the court must give it effect[.]" *Id.* Here, again, there is simply no evidence that a CGM is *not* "primarily and customarily used to serve a medical purpose." Indeed, the Secretary's conclusion otherwise is arbitrary and capricious. That should be the end of the inquiry.

Moreover, to the extent that the Court is even willing to consider the Secretary's proposed construction of "primarily and customarily used to serve a medical purpose", that construction is unreasonable. As the courts in *Whitcomb*, *Bloom*, and *Lewis* concluded, the Secretary has never offered a construction of the phrase that makes any sense or a reason to import the non-statutory/regulatory term "precautionary" (or even a logical meaning for that term).

To the extent the Secretary attempts to recast 42 C.F.R. § 404.202 to be limited to "serve a primary medical purpose" – rather than the actual language of "primarily and customarily used to serve a medical purpose" - again, as the courts in *Whitcomb*, *Bloom*, and *Lewis* found, that proposed construction is unreasonable, and arbitrary and capricious. The Secretary's position simply flies in the face of the regulation and constructions which contradict the regulation are unreasonable. *See, e.g., Common Cause*, 692. F,Supp. at 1396. It is to be expected, and the Secretary's prior regulations respecting multi-component systems confirm, that many medical conditions will require multi-component durable medical equipment to treat. And there is nothing in the statute or regulations limiting coverage to a single piece of durable medical equipment that, alone entirely treats and illness or injury. Stated alternatively, there is not substantial evidence to support the Secretary's conclusion otherwise.

Even taken on its own terms, there is still not substantial evidence to support the Secretary's claim that a CGM does not serve a "primary medical purpose."[9] As the courts in *Whitcomb*, *Bloom*, and *Lewis* found, only a CGM can provide the frequency of testing and trend information necessary for diabetics (especially brittle diabetics with hypoglycemic unawareness) to manage their diabetes and avoid death.

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[9] Though, again, this is not what the statute says.

Put simply, the idea that a CGM is not "primarily and customarily used to serve a medical purpose" is utterly baseless and at odds with reality. This is especially so in this case, where it is undisputed that one purpose of the CGM is to protect Mrs. Zieroth from life-threatening hypoglycemia. The sheer non-sensical nature of the result is one indication that the Secretary's position is without merit.

Moreover, the Secretary's claims regarding "precautionary", "adjunctive devices" or "the primary medical purpose" (Decision at 9-10; CMS 1682-R at 6-7) not being "durable medical equipment"/"primarily and customarily used to serve a medical purpose" actually conflict with the Secretary's other, pre-existing Decisions and Determinations. For example, the 1999 CMS Decision Memo approving Medicare coverage of continuing subcutaneous insulin infusion (CSII) pumps established "[t]he goal for diabetes treatment should be to obtain as close to normal blood glucose levels as possible." (CAG – 00041N – August 26, 1999 at 12-13). The same logic applies to CGM that provides the comprehensive 24-hour data necessary to properly program the CSII pump and that cannot be provided from limited finger sticks for a blood glucose meter. Also, pursuant to National Coverage Determination (NCD) 280.1, "digital electronic pacemaker *monitors*" are covered "durable medical equipment"/are "primarily and customarily used to serve a medical purpose." A pacemaker *monitor* would not meet any of the Secretary's newly proposed criteria (*i.e.*, the monitor serves a precautionary function to ensure proper functioning of the pacemaker, the monitor is adjunctive to the pacemaker itself and merely complements its operation, and the monitor does not serve the "primary medical purpose" of regulating cardiac pulses). A proposed construction of a statute/regulation that conflicts with pre-existing regulations is not reasonable. *See, e.g., Gerard v. N. Transp., LLC*, 146 F.Supp.2d 63, 67 (D. Me 2006) ("When such an interpretation, however, conflicts with binding law, such as

a regulation adopted after the notice and comment process established by the Administrative Procedure Act, 5 U.S.C. § 553, the Court need not give credence to the contrary interpretation.").

B. A CGM Is A "Blood Glucose Monitor" And Is "Primarily and Customarily Used to Serve a Medical Purpose"

If the Court determines that CMS 1682-R was issued in violation of law/improperly used as a basis to deny Mrs. Zieroth's claim, then the Court should simply reverse the Secretary's decision and order coverage without further analysis. This is so because the sole basis for CMS' referral, and Council's decision, was the alleged applicability of CMS 1682-R. Pursuant to 42 C.F.R. § 405.1110(c)(2), where (as here) CMS did not participate in the ALJ' hearing, then Council review is limited "to those exceptions raised by CMS." Thus, the Council review was limited to the issue of alleged applicability of CMS 1682-R. Accordingly, if the Court determines that CMS 1682-R is not applicable – either because it was illegally issued or is not supported by substantial evidence, is arbitrary and capricious, or for another reason – then no further analysis is necessary or proper.

Nevertheless, even without regard to CMS 1682-R, and considering on the base issue of whether a CGM is a "blood glucose monitor" and/or "primarily and customarily use to serve a medical purpose", then the Secretary's decision should also be reversed.

1. A CGM Is a "Blood Glucose Monitor"

As noted above, pursuant to 42 U.S.C. § 1395x(n) "durable medical equipment" specifically includes "blood glucose monitors." Thus, independent of efforts to separately construe "durable medical equipment", a CGM is a "blood glucose monitor" and is, again, covered under the statute.

There is not substantial evidence to support any claim that a CGM is not a "blood glucose monitor" within the meaning of the statute/that charge is arbitrary and capricious. Glucose in the

blood is carried by "interstitial fluid" to the cells and, as noted in CMS 1682-R itself, CGMs measure the glucose that is in the interstitial fluid. CMS 1682-R at 6. Thus, glucose levels in interstitial fluid are correlated with glucose levels in the blood itself. Accordingly, a measurement of interstitial glucose is an indirect measurement of blood glucose.

Nothing in § 1395x(n) limits "durable medical equipment" to "*direct* blood glucose monitors" and the Secretary's effort to import the word "direct" into the statute should be rejected. Indeed, traditional finger sticks/blood glucose monitors do not *directly* measure blood glucose. Instead, glucose in the blood reacts with glucose oxidase on a test strip and that reaction causes an uptake in oxygen, a color change, or an electrical signal. *See, e.g.*, "Glucose Meter" available at https://en.wikipedia.org/wiki/Glucose_meter#Continuous_glucose_monitors (accessed December 19, 2019); CMS 1682-R at 5." Measurement of the oxygen uptake, color change, or electrical signal is correlated with glucose levels in the blood. Thus, even traditional finger sticks/blood glucose monitors only indirectly measure blood glucose.

Because it is undisputed that traditional finger sticks/blood glucose monitors (which indirectly measure blood glucose) fall within the meaning of "blood glucose monitor" in the statute, the Secretary's effort to exclude CGMs by importing the word "direct" simply contradicts the statute, is not supported by substantial evidence, and is arbitrary and capricious.

A CGM is a "blood glucose monitor" within the meaning of 42 U.S.C. § 1395x(n) and is a covered benefit.

2. A CGM Is "Primarily and Customarily Used to Serve a Medical Purpose"

The idea that the FDA approved, life-saving, and continuous data device (that has no non-medical purpose and that is necessary to properly program a Medicare approved insulin pump) is not "primarily and customarily used to serve a medical purpose" is non-sensical on its

face. For the same reasons set forth above, there is simply no evidence (much less substantial evidence) that a CGM is not "primarily and customarily used to serve a medical purpose." For years, across multiple litigations, the Secretary has failed to articulate any other use for a CGM. Indeed, even the Secretary does not "question the … utility of the CGM to [Mrs. Zieroth]." Thus, the only evidence is that a CGM is "primarily and customarily used to serve a medical purpose." More generally, the Secretary's refusal to cover Mrs. Zieroth's CGM claim is arbitrary and capricious. In *Independent Petroleum Ass'n of Am. v. Babbitt*, 92 F.3d 1246, 1260 (D.C. Cir. 1996), the court stated:

> The treatment of cases A and B, where the two cases are functionally indistinguishable, must be consistent. This is the very meaning of the arbitrary and capricious standard.

As noted above, coverage of the functionally indistinguishable CGMs (indeed, the same CGM) was approved/ordered in the *Whitcomb*, *Bloom*, and *Lewis*' cases. Thus, the Secretary's effort to treat Mrs. Zieroth's case differently is, by definition, arbitrary and capricious.

The court in *Whitcomb* put it succinctly: "the threshold question of whether such monitors satisfy the regulatory definition of durable medical equipment should not vary from enrollee to enrollee." *Whitcomb,* at 15.

C. Coverage Should Be Ordered

Pursuant to 42 U.S.C. § 405(g) (fourth sentence):[10]

> The court shall have the power to enter, upon the pleadings and transcript of the record, a judgment affirming, modifying, or reversing the decision of the [Secretary], with or without remanding the cause for a rehearing.

As detailed above, because CMS' Referral and the Council's decision were, in relevant part, limited to and premised on the alleged application of CMS 1682-R, there is no other proper basis

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[10] As modified by 42 U.S.C. § 1395ff(b)(1)(A).

for denying Mrs. Zieroth's claim. Thus, if the Court concludes that the Council was in error in this regard, then there is nothing further to be done by the Council and the Court should just issue an Order requiring coverage and remand to the Council to effectuate the Court's decision.

III. CONCLUSION

For the reasons set forth above, the Court should hold that CMS 1682-R is invalid, reverse the Secretary's denial of Mrs. Zieroth's claim, and order the Secretary to cover Mrs. Zieroth's claim.

Alternatively, the Court should simply hold that a CGM is "durable medical equipment"/"primarily and customarily used to serve a medical purpose", reverse the Secretary's denial of Mrs. Zieroth's claim, and order the Secretary to cover Mrs. Zieroth's claim.

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Respectfully submitted,

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